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From: Michael A. Simmons

Lisa Glenn Lavery

Date: October 19, 2001

DRAFT – Preliminary and Tentative for discussion purposes only

### Benefits

#### *United States*

- Royalties should be eligible for active royalty exception of Subpart F.
- No tax on first drop-down in the United States; contribution of 100% of Spanish Operating Company into Spanish Holding Company 1, accompanied by check-the-box election for Spanish Operating Company should qualify as a tax free F reorganization.
- 50% of gain on Spanish Operating Company (Belmac) taxable in the United States on second drop-down to Spanish Holding Company 2. Gain is offset by expiring capital loss.

#### *Luxembourg*

- Swiss Branch subject to minimal tax in Luxembourg. Only 5% of branch profits subject to tax with depreciation deductions for intangibles allowed.
- No withholding tax on dividends paid from Luxembourg New Co. to Spanish Holding Company 2.
- Possibility of 1% capital tax in Luxembourg.

#### *Spain*

- No tax in Spain on contributions to Holding Company 1 & 2.
- No withholding tax on dividends paid from Spanish Holding Company 2 to Bentley.

#### *Switzerland*

- Swiss Branch subject to 1.9% tax (requires ruling).
- Treaty benefits:
  - 15% U.S. withholding tax on royalty payments from unrelated drug manufacturers located in the United States.
  - 0% withholding tax on royalty payments from unrelated drug manufacturers located in most EU countries – Luxembourg treaty will apply.

### Issues

- Need advice from Spain with respect to obtaining tax-free transfer of IP to Swiss Branch.

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- o Sale,
- o Declining royalty payments, or
- o Use EU Merger Directive to move the 'business' of IP.
- Need clarification regarding application of Luxembourg capital gain tax. Does EU Merger Directive grant an exemption?
- Need to obtain ruling for 1.9% tax in Switzerland.

cc: Wayne Smith  
Julie Oreto  
Jose Parafita  
Borja Escriva  
Cees Jorissen

BENTL003096  
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B511

**Bentley Pharmaceuticals, Inc.  
Management Meeting – 24 October**

TOPIC	SCHEDULE	PRIORITY
<p>1. Shire – Oral R&amp;D Licensing Collaboration Shire Executive Committee met on 10/17. Expected call by 10/20, but no call received to date. Draft license agreement pending. Need to call Jack Khattar (Shire) – Action: J. Horvath.</p> <p>Target contract date 11/15. Following detail applies:</p> <ul style="list-style-type: none"> <li>- Shire will do the in vitro/in vivo testing and BNT will license to them, 50/50 on new patents, 33 1/3% of milestone payments to BNT, 33 1/3% royalties to BNT. These figures are based “per compound”.</li> </ul>	Nov 15th	C
<p>2. Alcon – Ocular Regarding the Research Collaboration Plan, we need more info from Alcon (ophthalmic and intranasal). A planned meeting with Yvon Durant will also help. Order of business follows:</p> <ul style="list-style-type: none"> <li>- Find out what needs to be done with the formulation; meet with Yvon Durant on Tuesday, 10/31 - Action: B. Gyurik</li> <li>- Call Alcon NLT 11/17, after resolving plan for formulation - Action: B. Gyurik</li> <li>- Jordan reviewed draft MTA and returned on Friday, 10/20. Awaiting response prior further action - Action: J. Horvath</li> <li>- Conduct lawyer-lawyer conf. call with Alcon - Action: J. Horvath</li> </ul>	1 <sup>st</sup> Qtr 2001	B
<p>3. Schering-Plough (Phase 2B) - Toenail Laquer S-P Ops Committee meeting 10/23 on Health Care w/ Mark Kiwin was rescheduled to Friday, 10/27. Jordan talked to Nancy Miller-Rich on Monday, 10/23. Nancy showed some concern that BNT is collaborating with other companies as well. Wants until Monday, 10/30 to respond. BNT is upfront about working with others more advanced in this effort (i.e., McNeil).</p> <ul style="list-style-type: none"> <li>- Further progress on agreement pending 10/30 call back from Nancy - Action: J. Horvath</li> <li>- Initiate Hart-Scott-Rodino after agreement completed - Action: J. Horvath</li> </ul>	Nov/Dec '00	A
<p>4. Insulin - Development Issues a) Supply – Sources (TBD). Obtain a contingency supply of insulin. Order of business:</p> <ul style="list-style-type: none"> <li>- Jim replied to Atul 10/19 email and Atul responded. They confirmed manufacturing capability with Piramal. Meeting planned with Atul and Ms. Piramal 11/7-9 in Atlanta - Action: J. Murphy and B. Gyurik</li> <li>- Visit to Bombay scheduled for 11/20. Jim and Bob G. to visit Piramal to negotiate supply and inspect for GMP compliance - Action: J. Murphy / Bob Gyurik</li> <li>- Pacific Rim – Follow on to Piramal visit will be visit to Taipei and Singapore for other sources of insulin, et al. Jim, Bob G. and YungTai Tsu to make the trip.</li> </ul> <p>Phone Numbers for Atul Parvatiyar: Home: 770 931-8821 Cell: 678 427-1679 Office: 404 327-9100</p> <p>b) Regulatory 1) Pre-Clinical:</p> <ul style="list-style-type: none"> <li>- Contact John Cullen - Action: B. Gyurik</li> <li>- Talk to Roger Wells - Action: B. Gyurik</li> </ul>	NLT Nov 30th	A

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TOPIC	SCHEDULE	PRIORITY
<ul style="list-style-type: none"> <li>- Brenda, Bob S. and Bob G., Fred Reno – For planning</li> </ul> <p>2) Clinical:</p> <ul style="list-style-type: none"> <li>- Enlist support of Sherwyn Schwartz - Action: B. Gyurik</li> <li>- Enlist support of Dartmouth Medical</li> </ul> <p>3) CMC:</p> <p>c) Formulation/Development</p> <ul style="list-style-type: none"> <li>- Call Mayron. Mayron needs to start at square one. This issue deferred until after meeting with Yvon Durant on 10/31 - Action: B. Stote</li> <li>- Call UWVa for formulation assistance - Action: J. Murphy</li> <li>- Meet with Yvon Durant on Tuesday, 10/31 to discuss intranasal insulin - Action: B. Stote, B. Gyurik, J. Murphy, P. Fitzgibbons</li> <li>- Call Scandinavian Biopharm for Novo Nordisk supply of insulin - Action: J. Murphy</li> </ul>		
<p>5. Bristol-Myers Squibb</p> <ul style="list-style-type: none"> <li>- Call Joe Loftus today (10/24) and suggest that they amend current IND and we will formulate for them - Action: J. Murphy. We will produce clinical supplies as another leg on their clinical study.</li> <li>- Need to schedule a meeting at Princeton after contact to discuss technology; transfer - Action: B. Gyurik, P. Fitzgibbons and Y. Velazco</li> </ul>		B
<p>6. Auxillium A2 - Testosterone</p> <ul style="list-style-type: none"> <li>- Regulatory issues. John Cullen and Brenda Stoelze to meet and discuss, then meet with Bob Stote - Action: B. Stoelze</li> <li>- Call Dave Brusick to design PK animal study - Action: J. Murphy</li> <li>- PK Study for Radiolabel CPE-215 - Action: P. Fitzgibbons</li> <li>- Prepare second amendment with patch included in agreement. Jordan sent out draft amendment to Auxillium lawyer; waiting for response - Action: J. Horvath</li> </ul>		B
<p>7. Dartmouth License – Testosterone</p> <p>Issues of schedule and royalty/milestone payments were discussed and resolved. Jordan to call and give concurrence on wording. Will advise all by email. Expect to complete in 2-3 days – Action: J. Horvath.</p>	Oct 27	A
<p>8. Pfizer - Animal Studies (CPE 215 formulations). DONE!</p> <ul style="list-style-type: none"> <li>- Veterinary in U.S. is underway</li> <li>- Veterinary in Sandwich, UK is underway</li> <li>- Human program was approved on Friday, 10/20</li> <li>- Mike to call Keith Horspool to verify need for purchase order prior invoicing for \$40k for new agreement for another 8 formulations. Also to check on payment for prior agreement – Action: M. Price</li> <li>- Note: Insulin development concern from Pfizer</li> </ul> <p>Note: Jim/Bob G. need to ask Mark Beccarelli (Easterly UK office) re. patches</p>		A
<p>9. Wyeth - Nail Laquer</p> <p>Wyeth asked for a product profile on nail laquer. Need to schedule a presentation for them at Wyeth within 30 days - Action: B. Gyurik and J. Murphy</p>		B

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**Bentley Pharmaceuticals, Inc.  
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TOPIC	SCHEDULE	PRIORITY
10. Shire Product Sale – Controlvas Draft documents were reviewed and delivered last Thursday, 10/19. A couple of changes to be made and delivered to the other side. Continue to monitor – Action: J. Horvath		A
11. Mexico - Omeprazole - Legal Issue- Review contract with Laboratorios Columbia- Action: J. Horvath - Business Issue- Alert management that further supply issues may develop. Jim to relay message to Spain that w/o Jordan's review - Action: J. Murphy  Jim to handle during visit to Ethypharm in Nov.		A
12. Italpharmaco (Portugal) - Omeprazole and Enalapril Outlicensing issue  Jim to handle during visit to Ethypharm in Nov.		A
13. Helm AG - Omeprazole Jim/Jordan contract issue for outlicensing  Jim to handle during visit to Ethypharm in Nov.		A
14. Teva - Generics Three day meeting with Teva taking place now. Potential regulatory approval for first 13 new generics - Teva to perform due diligence review of Omeprazole patents prior to European License from Lab. Belmac  Jim to handle during visit to Ethypharm in Nov.		A
15. Dartmouth Programs - Onychomycosis – Find investigator – Action: B. Gyurik/Alla Kahn - Insulin – Find Investigator – Action: B. Gyurik - FMS/CFS: Initiating State grant for testing (Testosterone and non-testosterone) Bob G. called Alla Kahn and is currently waiting for response.		
16. UNH – GnRH Discussions with Stacia Sower (PI at UNH) continuing. Agreement is now being modified for use of mice vice lamprey eels.		B
17. Knoll Pain Mgt - Insulin, diclofenac gel, oxycodone nasal, hydrocodone nasal Invited us for pain management brainstorming session in New Jersey end of Nov (Gyurik, Stote, Murphy)		B
18. Repligen - Secretin intranasal Contact Walter Hurlihy - Action: J. Murphy		B
19. Radiolabel CPE-215 Talk to panel of experts - Action: J. Murphy		B

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TOPIC	SCHEDULE	PRIORITY
20. Allergan - Ocular CPE-215 formulations Call Frank Pinkerton for introduction to President - Action: J. Murphy Jim sent ocular package to Humphreys last Friday, 10/20		B
21. McNeil - Nail laquer Present nail laquer to Manny Lopez at Fort Washington (Valley Forge, PA) during week of Oct 23 <sup>rd</sup> - Action: J. Murphy and B. Gyurik  Jim is meeting with them this Thursday, 10/26		
22. Paracetamol - Promotion of new patent needed. Call McNeil, Pharmacia UpJohn and Wyeth- Action: J. Murphy - Patent attorneys are reviewing on 10/30 - Press release scheduled for week of 11/6	Nov 10	
23. Bertek - On-going evaluations		
24. Lohmann - Testosterone patch alternative Bob Gyurik to keep them happy for time being		
25. Duke- Vaccines Call Herman Staats 10/18 re. testing in mice with intranasal vaccines. Set up meeting for week of 10/23 - Action: B. Gyurik - Need consulting agreement - Action: J. Horvath - Need input on MTA (sent out last week, pending response) - Action: J. Horvath		

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Spain

Lactulose Sed For 30 mil pstat  
 Lab. Vinto sold US lansoprazole patent  
 Omeprazole patent - Announce  
 Simvastatin

% 22 reduction

\$ 79 mil mkt.

Lab Bel

Lab Davul

LAUNCH 1st Qtr.

None on mkt

Agreed to license to other Europe Cos.

Lab Belmac will manufacture

For other (Supply Agmt)

Ciprofloxacin

2 mil / wk = 8 mil / Month

20 Tablets = 800 = \$4.00

15.00 x 16.00

Quote to USA.

TABLETS  
 Dosage levels 10 mg  
 20 mg  
 40



B516

31 October 01

EDMUND CHAVEZ

Wants to raise money 201 406 2635

Spain 31 October - Adolfo Patent Understood

1. New Patent - Aqueous pellets, process  
Monday - Filing2 Organic Patent - P-200100825  
Ethypharm - Not public4th to be submitted New Patents - Tablets - Last year (Proceeding)  
Aqueous doing Extension P-??? Next week2nd submit Submitted P-2000002797  
Omepr Tablets - direct comparison1st submission submitted P-200002665  
Gen. Proceeding - Vacuum  
Granulation for other  
products3rd sub. Organic Patent P-200100825 - submitted  
Ethypharm

5th Patent DZC-2001

New Proceed for tablets - Direct Compar

More stable  
Efficient  
Cheaper  
Less degradation



B517

234 TOTAL

LAB. BEIMAC	85	220-225
LAB. DAVIE		
LAB. RIMMANN	5.1	200
		425
NEW OFFICE		80
		<u>505</u>

Bob Moran 31 OctoberAcquisition  
Letter of TRUSTSpain

20 TONS  
4000 ft  
OMEprazole 5-6 - 160 mil pph  
Nov 8-10 8th Apr  
8/mo

Alliquia 50K Boxes/Mo 200 mil pph  
Simvastatin  
8 customers + export  
60-70 mill profit.

Aspirin

25 mill pph

Reduction of cost Ompend

Per kg 30K → 17K

Plus equipment

Savings  
270 mil

7 Batches = 2 tons/mo.

111



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**Bentley Pharmaceuticals**  
**Project Status Report – November 6, 2001**

PROJECT AND STATUS	ACTION
<p>1. Pfizer</p> <ul style="list-style-type: none"> <li>Current Actions: <ul style="list-style-type: none"> <li>First JWC meeting (7 Nov) postponed until 9 Nov. Bob and Paul to attend. Paul preparing draft budget. Fully signed agreement pending.</li> <li>Dermtech - received proposal from Dermtech, proposal to be discussed at JWC meeting with Pfizer.</li> </ul> </li> </ul> <p><u>Note:</u> Basic Agreements pending/planned: 1) Research Collaboration Agreement; 2) License (or Platform) Agreement; and 3) Subscription (investment) Agreement.</p>	<p>Bob/Paul attend JWC Meeting, get signed agreement</p> <p>Bob continue to coordinate with Dermtech</p>
<p>2. GlaxoSmithKline (GSK)</p> <p>a) GSK (North Carolina) - Insulin</p> <ul style="list-style-type: none"> <li>Joel emailed Jim: internal debate on insulin. No consensus yet. Mid-Nov for further decisions.</li> </ul> <p>b) GSK (Phila) – Musclar-Skeletal products</p> <ul style="list-style-type: none"> <li>Jim, Bob G. and Paul met with Chau-Pin Lee in Collegeville, PA on 17 Oct. Looking for help on one <u>unspecified</u> drug. Need 1 mg delivered with 30 min on-set of action, transdermal or intranasal delivery. They are early-on in a long-haul project. Difficult at best and not high priority for us at this point. GSK discussing internally and they will get back to us.</li> </ul>	<p>Jim monitor</p> <p>No action at this time</p>
<p>3. Insulin – Development Issues</p> <p>a) <u>Supply</u> – Insulin supply from Diosynth. All OK for now.</p> <p>b) <u>Clinical Trials</u> - Phase I trial: Proof of Principle (normals), followed by the Phase II trial: Type 1 and 2 diabetics</p> <ul style="list-style-type: none"> <li>Phase I at UNH Center for Health Enhancement (CHE) <ul style="list-style-type: none"> <li>UNH IRB approval of protocol pending one outside reviewer from Dartmouth IRB. Bob S. monitor.</li> <li>Paul working with UNH (Vic Sosa) for clinical trial contract and Tony T. for budget</li> <li>Bob S. working insurance coverage (Tom Wilde)</li> </ul> </li> <li>Schwartz Lab <ul style="list-style-type: none"> <li>Project on hold pending completion of trial at CHE.</li> </ul> </li> </ul> <p>d) <u>Regulatory</u></p> <ul style="list-style-type: none"> <li>IND will be submitted prior to follow-on Phase I/II with Schwartz Lab</li> </ul>	<p>Paul pursue contract &amp; budget.</p> <p>Bob S. work trial insurance.</p> <p>Bob Stote keep in touch with Schwartz lab.</p>
<p>4. Bio-Concept Laboratories</p> <ul style="list-style-type: none"> <li>Sterile actuator issue: putting thru another two week study to evaluate</li> <li>Received excellent progress report covering work to date.</li> </ul> <p><u>Note: Future ophthalmic research:</u> They asked for separate IP agreement in preparation for their submission of an SBIR by 1 Dec. <u>Need to discuss/resolve this, as we have no basic agreement with them as yet.</u></p>	<p>Bob/Paul continue to monitor progress</p> <p>Jim/Jordan to visit Frank Smith to talk ophthalmic collaboration</p>

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## Bentley Pharmaceuticals Project Status Report – November 6, 2001

PROJECT AND STATUS	ACTION
<b>5. Novartis</b> <ul style="list-style-type: none"> <li>▪ Anti-fungal lacquer <ul style="list-style-type: none"> <li>- Jim to talk to Bob Nissen today. Key factors are: 1) binding LOA (term sheet); 2) upfront cash needed ; 3) milestones; 3) royalties; 4) equity investment in Bentley ; and 5) timing.</li> <li>- Novartis wants to be involved in study design. Meeting at Novartis being planned for 19 Nov. (Bob Stote coordinating with Helmut Albrecht).</li> <li>- Need to resolve type of study: pilot or pivotal, cost, timeline, location for study. (Need to determine best course of action for U.S./Canada and Spain trials)</li> </ul> </li> <li>▪ Paracetamol (acetaminophen) - Jim also sent them summary data on clinical evaluation of paracetamol. Potential interest in sachet form.</li> </ul>	<p>Jim discuss with Bob Nissen</p> <p>Bob Stote confirm meeting with Helmut Albrecht</p> <p>Monitor any further interest with paracetamol</p>
<b>6. Gupta Clinical Trial</b> <ul style="list-style-type: none"> <li>▪ Bob to talk to Gupta this Friday to postpone 21 Nov visit to his lab. Reschedule any day Dec 10-13 if possible. Decision to conduct trial pending outcomes with Novartis (and possibly others).</li> </ul>	Bob G. reschedule visit to Gupta lab in Toronto
<b>7. Spain Phase III Lacquer Trial</b> <ul style="list-style-type: none"> <li>▪ Bob Stote and Paul talk to Nieves Hernando about requirements in Spain and discuss type of trial (Clotrimazole, ciclopirox, placebo?)</li> </ul>	Bob S. and Paul talk to Nieves
<b>8. Auxilium A<sup>2</sup></b> <ul style="list-style-type: none"> <li>▪ Testosterone in Men – Phase 3 in progress. Last patient planned on 19 Oct. NDA submission planned for 31 Dec. Reference country to be chosen at time of filing NDA.</li> <li>▪ Stanolone (DHT) – They are awaiting the 30 day stability on 6 formulations sent to them, will then go into Yucatan pigs, and then select 2 formulations to go into man with before making an acceptance decision.</li> <li>▪ Oxycodone – Bob G. to send them the oxycodone formulation that failed so they can look at it and then prepare to go to the next step.</li> </ul>	<p>Bob S. monitor Testo progress</p> <p>Bob S / Bob G monitor DHT progress</p> <p>Bob G. send oxy formulation</p>
<b>9. UAB Nail Lacquer Clinical Study</b> <ul style="list-style-type: none"> <li>▪ Anti-fungal nail lacquer – Phase I/II Trials on-going at UAB. Latest update received from Wendy: <u>31 Oct</u>. Continue to monitor results.</li> </ul>	Bob S. monitor progress
<b>10. Dartmouth-Bentley NHIRC Grant – Testosterone in women with Fibromyalgia (FMS)</b> <ul style="list-style-type: none"> <li>▪ First 6 patients scheduled for final screening with Dr. Lin Brown, 5-9 Nov.</li> <li>▪ Clinical Trial is for 28 days with each patient</li> <li>▪ First 6 patients start trial together on Saturday 10 Nov with final blood draws on Day 28, Saturday 9 Dec. Other patients are needed: target of 12 patients total.</li> </ul>	Bob/Paul monitor progress
<b>11. UNH Projects – Summary</b> <ul style="list-style-type: none"> <li>▪ Project 1- Yvon Durant: Intranasal delivery, membrane transport. Most likely need to extend this, even if we fund it alone. Will look for NHIRC extension.</li> <li>▪ Project 2 – Roger Wells: Delivery studies (pigs: testo, DHT, GnRH)</li> </ul>	Bob G./ Paul monitor progress

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**Bentley Pharmaceuticals**  
**Project Status Report – November 6, 2001**

PROJECT AND STATUS	ACTION
<ul style="list-style-type: none"> <li>Project 3 – Stacia Sower: Peptide delivery (GnRH transdermally and intranasally. (Note: Roger Wells working in conjunction with Stacia to conserve resources)</li> </ul>	
<p>12. Reckitt-Benckiser</p> <ul style="list-style-type: none"> <li>Reformulating paracetamol sachet for taste masking. Asked for more samples with different flavoring. Expect decision by mid-November.</li> </ul>	Jim/Adolfo keep in touch with Reckitt
<p>13. Sanofi Synthelabo - Paracetamol tablets</p> <ul style="list-style-type: none"> <li>Reformulating again for faster dissolution</li> </ul>	Jim / Adolfo monitor
<p>14. CPE-215 EDMF – Haarmann &amp; Reimer (H&amp;R)</p> <ul style="list-style-type: none"> <li>EDMF: Currently not pursuing EDMF for CPE-215</li> <li>Need to complete the CDA with them.</li> </ul>	Jordan respond to H&R on CDA
<p>15. New Patents</p> <ul style="list-style-type: none"> <li><u>Patents – Spain</u> <ul style="list-style-type: none"> <li>1<sup>st</sup> Patent – Submitted P-2000,02685 (General procedure – Vacuum and Granulation for other products.</li> <li>2<sup>nd</sup> Patent – Submitted P-2000,002797 (Tablet formulation for Omeprazole and other gastric sensitive drugs – Direct compression.</li> <li>3<sup>rd</sup> Patent – Organic formulation process for Omeprazole. Patent P-2001,00825. (also protection from Ethypharm).</li> <li>4<sup>th</sup> Patent – Aqueous Process - a patent extension of the tablet formulation patent from last year (P-2000,002797). To be submitted early November 2001.</li> <li>5<sup>th</sup> Patent – New procedure for tablets – direct compression. Plan to submit in December 2001.</li> <li>PCT for Paracetamol filed</li> </ul> </li> <li><u>Patents – Bentley</u> <ul style="list-style-type: none"> <li>Intranasal Insulin Patent – Bob G. filed the provisional in U.S. in June '01.</li> <li>Lacquer PCT Patent issued 23 Aug; all claims allowed</li> </ul> </li> </ul>	<p>Continue to monitor</p> <p>Press release on Spain patents soon</p>
<p>16. Insurance Issues</p> <ul style="list-style-type: none"> <li>Mike sent summary of coverages in Europe to Tom Wilde (Gallagher Insurance). Wilde will review this, and he will also talk to</li> <li>Issue of confidentiality – Are insurance companies bound by confidentiality?</li> <li>Insulin trials insurance – Need to send contract/agreement to Tom Wilde with agreed upon insurance/indemnity clauses.</li> </ul>	<p>Mike follow-up on confidentiality question</p> <p>Paul working contract with UNH</p>
<p>17. BOD Meeting Schedule</p> <ul style="list-style-type: none"> <li>Next BOD Meeting is 7-8 Nov in Philadelphia, PA. Mike has the agenda. Jim to provide his presentation evening of 7 Nov.</li> <li>Jan 30<sup>th</sup> is date for the winter meeting in Spain (fly out separate flights 28<sup>th</sup> or 29<sup>th</sup>)</li> </ul>	Attend meeting

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## Bentley Pharmaceuticals Project Status Report – November 6, 2001

PROJECT AND STATUS	ACTION
<b>18. Tax Planning</b> <ul style="list-style-type: none"> <li>Local Tax – Conference call occurred Friday 12 Oct with Mike/Jordan and Brian Gallagher, and Deloitte &amp; Touche. Follow-up conference call planned.</li> <li>Federal / Int'l Tax – Need to look at tax consequences of transferring IP from subsidiary (Spain) to parent (Bentley). Brian Gallagher looking into this.</li> </ul> <p><b>Note: Tax Planning is on agenda for BOD meeting 7-8 Nov</b></p>	Mike / Jordan discuss prior to BOD meeting
<b>19. Cambrex</b> <ul style="list-style-type: none"> <li>Discussion/negotiation in progress. Various funding proposals being discussed: <ul style="list-style-type: none"> <li>Cambrex wants to take a 9.9% interest in Bentley.</li> <li>Cambrex provide ½ cash funding upfront along with our dossiers, ANDAs, and IP</li> <li>Cambrex providing stock (potential selling by Bentley for cash)</li> <li>Jim proposed \$5M per year for 5 yrs</li> <li>Provide a list of our Spanish products as candidates for generic submission in U.S. under the JV.</li> </ul> </li> </ul>	Define what we want from them after BOD meeting, then provide term sheet
<b>20. RIT (GSK in Belgium) – Vaccines:</b> Bob Stote follow-up with RIT	Bob Stote follow-up with RIT
<b>21. Bristol Myers Squibb – Review of lacquer coming up.</b> CDA is pending. BMS moving very slowly.	Jordan track CDA
<b>22. Chatham</b> <ul style="list-style-type: none"> <li>Pending meeting to discuss lacquer (OTC) and other topicals (diclofenac). Need to send information, product profiles. Emphasize paracetamol.</li> </ul>	Send info to them
<b>23. Ciprofloxacin</b> <ul style="list-style-type: none"> <li>Jordan spoke with Senator Smith staffer who deals with DoD, no further progress.</li> <li>Paul to call Dept of Defense agency to check on policy of DoD purchasing non FDA approved drugs.</li> </ul>	Paul call DoD for policy info
<b>24. Pharmacia &amp; UpJohn</b> <ul style="list-style-type: none"> <li>Pharmacia has expressed strong interest in our lacquer</li> <li>Paul sent list of Pharmacia/Searle drugs for application of CPE-215 sent to Herb Brotspies</li> <li>Due diligence visit to Bentley scheduled for 26 Nov.</li> </ul>	Prepare for due diligence visit
<b>25. Herron</b> <ul style="list-style-type: none"> <li>Wants to license paracetamol for Australia and Pacific Rim. Adolfo sent term sheet.</li> </ul>	Adolfo action
<b>26. Procter &amp; Gamble</b> <ul style="list-style-type: none"> <li>Called to ask for our help to test a topical product (regional, non-systemic, lipophilic tendencies, 200-300 MW)</li> <li>Need to complete CDA and MTA</li> </ul>	Jordan complete CDA
<b>27. DUSA Pharm.</b> <ul style="list-style-type: none"> <li>Visited us 26 Oct. Interested in photo-active compounds with CPE-215.</li> </ul> <p>CDA completed.</p>	Jim monitor

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B522



**Bentley Pharmaceuticals**  
**Project Status Report – November 6, 2001**

PROJECT AND STATUS	ACTION
28. Perrigo Pharm. <ul style="list-style-type: none"><li>▪ Interested in topical NSAIDs. CDA sent to them.</li></ul>	Jim monitor
<b>END LIST- OTHER POTENTIALS</b> McNeil – Lacquer Schering AG (Berlex in U.S.) – Derm. products, HRT PLR – Potential switch to other firm TEVA – Potential acquisition of Bayvit	

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B523

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 \*\*\* REPORTE DE TX \*\*\*  
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TRANSMISION OK

N° TX/RX	2055
TELEFONO CONEXION	0016039646888
SUBDIRECCION	
ID CONEXION	
HORA COM	14/11 18:24
TP USADO	01'25
PAG.	2
RESULTADO	OK

TO: Mr. MURPHY.

FROM: ADOLFO HERRERA

LABORATORIOS ETHYPHARM, S.A.  
 D. Adolfo de Basilio  
 C/ Marqués de la Ensenada, 16  
28004 MADRID

Madrid, 14 November 2001

Dear Sirs,

We address to you in your capacity of one of the signing parties in the "Manufacturing Agreement" of micropellets of Omeprazol, subscribed on 23 March 2000.

Taking advantage of the power granted in the clause G of the mentioned agreement and in accordance with the stipulated notice, we hereby let you know our resolution to terminate the mentioned manufacturing agreement of Omeprazol, being the formal notice given 4 (four) months in advance regarding the term of the same, the 23<sup>rd</sup> of March 2002.

In the foregoing of the above, we state that from the said date the manufacturing agreement once and again mentioned should be declared finished.

Yours faithfully,

Adolfo Herrera  
 Director General

BEL051569  
 CONFIDENTIAL



B524

TO Mr MURPHY.

FROM ADOLFO HERRERA

LABORATORIOS ETHYPHARM, S.A.

D. Adolfo de Basilio

C/ Marqués de la Ensenada, 16

28004 MADRID

Madrid, 14 November 2001

Dear Sirs,

We address to you in your capacity of one of the signing parties in the "Manufacturing Agreement" of micropellets of Omeprazol, subscribed on 23 March 2000.

Taking advantage of the power granted in the clause G of the mentioned agreement and in accordance with the stipulated notice, we hereby let you know our resolution to terminate the mentioned manufacturing agreement of Omeprazol, being the formal notice given 4 (four) months in advance regarding the term of the same, the 23<sup>rd</sup> of March 2002.

In the foregoing of the above, we state that from the said date the manufacturing agreement once and again mentioned should be declared finished.

Yours faithfully,

Adolfo Herrera

Director General

P.D. Since the Manufacturing Agreement of micropellets of Omeprazol dated on 23<sup>rd</sup> March 2000, will become resolved on 23<sup>rd</sup> March 2002, we advise you, that from that date onwards, we remain disposed, if you request it, to discuss with you a new Manufacturing Agreement, whereby, taking into consideration the current circumstances -other than the ones that induced the agreement of the year 2000-, the needs of Laboratorios Ethypharm, S.A. become fully satisfied.

BEL051567  
CONFIDENTIAL

B525

LABORATORIOS ETHYPHARM, S.A.  
D. Adolfo de Basilio  
C/ Marqués de la Ensenada, 16  
28004 MADRID

Madrid, 14 November 2001

Dear Sirs,

We address to you in your capacity of one of the signing parties in the "Letter of Intent", subscribed on 23 March 2000.

Taking advantage of the power granted in the Specification 3 of the mentioned Letter of Intent and in accordance with the stipulated notice, hereby we let you know our resolution to terminate the mentioned Letter of Intent, being the formal notice given 4 (four) months in advance regarding the term of the same, the 23<sup>rd</sup> of March 2002.

In the foregoing of the above, we state that from the said date the Letter of Intent once and again mentioned should be declared finished.

Yours faithfully,

Adolfo Herrera  
Director General

BEL051568  
CONFIDENTIAL



Laboratorios Belmac, S.A.

LABORATORIOS ETHYPHARM, S.A.  
D. Adolfo de Basilio  
C/ Marqués de la Ensenada, 16  
28004 MADRID

Madrid, 14 de Noviembre de 2.001

Muy Señores nuestros:

Nos dirigimos a Vdes. en su calidad de contraparte del "Contrato de Fabricación" de microgránulos de OMEPRAZOL, suscrito el 23 de Marzo de 2.000.

Haciendo uso de la facultad que nos concede lo dispuesto en el apartado G del citado Contrato y cumpliendo con el preaviso pactado, por la presente les comunicamos nuestra decisión de denunciar el mencionado Contrato de Fabricación de microgránulos de OMEPRAZOL, denuncia que se efectúa con más de cuatro (4) meses de antelación al 23 de Marzo de 2.002.

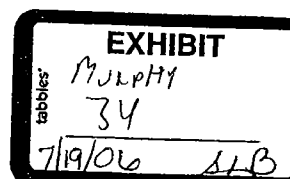
En consecuencia, les manifestamos que desde la citada fecha deben considerar extinguido a todos los efectos el Contrato de Fabricación, reiteradamente mencionado.

Atentamente,

LABORATORIOS BELMAC, S.A.

Adolfo Herrera  
Fdo.: Adolfo Herrera Málaga  
Director General

P.D. Dado que el "Contrato de Fabricación" de microgránulos de OMEPRAZOL de 23 de Marzo del 2000 quedará extinguido el 23 de Marzo de 2002, les comunico que, desde este momento, estamos a su completa disposición para negociar con Vdes. un nuevo Contrato de Fabricación en el que, teniendo en cuenta las actuales circunstancias -distintas a las que motivaron el contrato del 2000-, se satisfagan plenamente las necesidades de Laboratorios Ethypharm, S.A.



EP 002929



### AFFIDAVIT OF ACCURACY

This is to certify the document, <sup>2000</sup> Correspondence regarding Manufacturing contract of March 23, 2003, has been translated from Spanish into English by staff members of TransPerfect Translations familiar with both the Spanish into English languages and is to the best of our knowledge, ability and belief, a true and accurate translation.

A handwritten signature in dark ink, appearing to read 'Susan Christian', is written over a horizontal line.

Susan Christian  
TransPerfect Translations, Inc.  
15 Broad St., Suite 305  
Boston, MA 02109

Sworn to before me this  
29th day of October 2004

A handwritten signature in dark ink, appearing to read 'Notary Public', is written over a horizontal line.

Signature, Notary Public  
Commonwealth of Massachusetts  
Commission Expires August 14, 2009

[logo]

Laboratorios Belmac, S.A.

LABORATORIOS ETHYPHARM, S.A.

Mr. Adolfo de Basilio

Calle Marqués de la Ensenada, 16

28004 MADRID

Madrid, November 14, 2001

Dear Sirs,

We are writing to you in your capacity of counterpart under the "Manufacturing Contract" of OMEPRAZOL microgranules, signed on March 23, 2000.

Using the right granted to us under section G of said Contract and complying with the notice mandated therein, we are hereby communicating our decision to cancel said Manufacturing Contract of OMEPRAZOL microgranules, which notice of cancellation is issued more than four (4) months before March 23, 2002.

Consequently, we indicate that as of said date, you must consider the Manufacturing Contract mentioned above cancelled for all purposes.

Sincerely,

[signature]

Adolfo Herrera

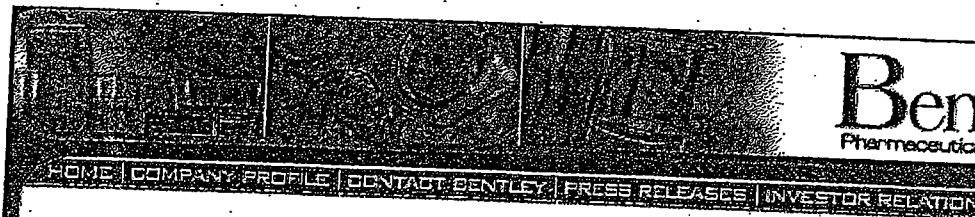
General Director

P.S.: Since the "Manufacturing Contract" of OMEPRAZOL microgranules of March 23, 2000 will be cancelled on March 23, 2002, I am communicating that, as of now, we are completely available to negotiate with you a new Manufacturing Contract in which, taking into account the current circumstances—which are different than those that motivated the 2000 contract—the needs of Laboratorios Ethypharm, S.A. may be fully satisfied.

[see original for address information]

Bentley Pharmaceuticals

Página 1 de 1



## press releases | press releases

### BENTLEY PHARMACEUTICALS FILES FOUR NEW PATENTS FOR IMPROVED ORALLY-DELIVERED PRODUCTS, INCLUDING OMEPRAZOLE AND LANSOPRAZOLE Nov 14, 2001

NORTH HAMPTON, NH, Nov. 14 -- Bentley Pharmaceuticals, Inc. (AMEX: BNT), a drug delivery company with a commercial presence in Europe, announced today that through its wholly-owned Spanish subsidiary, Laboratorios Belmac, it has submitted four new patents over the past year for improved formulations of orally delivered products. The patents cover:

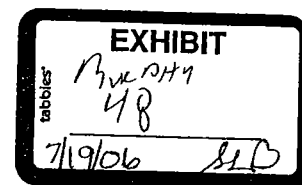
- New Aqueous Formulations of Omeprazole and Lansoprazole Utilizing Engineered Advancements in Manufacturing of Pellets.
- Procedures For Improved Pellets of Stable Omeprazole and Other Gastro-Intestinal Pellets.
- New Galenic Omeprazole Formulations in Tablets: Procedure for Preparation and Application in Human and Veterinary Medicine.
- Procedure for Vacuum Production of Pharmaceutical Preparations of Controlled-Release and Gastro-Resist

James R. Murphy, Chairman and CEO, said, "These patents describe new technological processes and spe to create new methods for manufacturing products that are sensitive to humidity and temperature. The innovative, the manufacturing process that renders omeprazole, lansoprazole and other products more st protecting active substances from gastric degradation. The result is a dramatically reduced time associat manufacturing process as well as lower costs of production. These advancements in orally administered p Bentley's commitment to delivery-enhanced therapeutics by going beyond its patented technology in tran transmucosal, and ocular products. We are pleased to announce another milestone that will help Bentley and effectively compete in what is becoming a crowded generic market."

Bentley Pharmaceuticals, Inc. is a drug delivery company focused upon improving the absorption of a wid and peptides through proprietary drug delivery technologies, which it intends to commercialize in the U.S. markets by licensing to other pharmaceutical companies. Bentley also manufactures and commercializes generic products in Europe for the treatment of cardiovascular, gastrointestinal, neurological and infectiou through its subsidiaries Laboratorios Belmac and Laboratorios Davur.

*Safe Harbor Statement under the Private Securities Litigation Reform Act of 1995: The statements which facts contained in this press release are forward-looking statements that involve certain risks and uncert but not limited to risks associated with the uncertainty of future financial results, additional financing req ability to find effective market distribution channels, development of new products, regulatory approval p impact of competitive products or pricing, unpredictability of patent protection, technological changes, th economic conditions and other uncertainties detailed in the Company's filings with the Securities and Exc Commission.*

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## CONFIDENTIALITY AGREEMENT

This CONFIDENTIALITY AGREEMENT is made and effective as of this first day of November 14th, 2001, between **LABORATORIOS BELMAC S.A.** (the "Disclosing Party") and **PHARMALLIANCE.** (The "Receiving Party").

The Disclosing Party intends to disclose to the Receiving Party certain information, ideas, tangible material, and other knowledge concerning technical studies over the processing of PELLETS OF OMEPRAZOL, procedures, galenic formulation on pharmaceutical drugs, Bioequivalences Studies and in particular, any information given during the relations between the companies.

Any information given to the other company relative to PELLETS OF OMEPRAZOL will be considered as " **Confidential Information** ".

All of which the Disclosing Party considers to be trade secrets and / or confidential information owned by the Disclosing Party .The Receiving Party wants to receive the Confidential Information to evaluate whether to enter into a business transaction with the Disclosing Party.

THEREFORE, intending to be legally bound and in consideration of the mutual covenants contained herein, Disclosing Party and Receiving Party agree as follows:

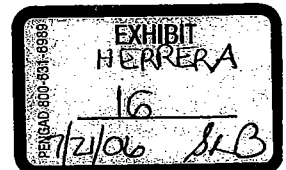
1. -Confidential Information shall be subject to the terms of this Agreement when

- (a) it is marked " Confidential ", if disclosed in written form ; or
- (b ) it is identified by the Disclosing Party as confidential at the time it is disclosed, if disclosed in oral , written, visual or tangible form; or
- (c) the Receiving Party has reason to believe that the Disclosing Party considers the information confidential at the time it is disclosed.

2. -The Receiving Party shall not use the Confidential Information, directly or indirectly, for any purpose other than evaluating whether to enter into a business transaction with the Disclosing Party. The Receiving Party shall obtain the prior written consent of the Disclosing Party prior to disclosing any of the Confidential Information to any third party.

3. -The confidentiality and non disclosure obligations set forth herein shall not apply to:

- (a) information which the Receiving Party can prove by suitable written documentation was already developed by or on behalf of the Receiving Party , or was in its possession prior to receipt from the Disclosing Party ; or
- (b) information which the Receiving Party can show was received by it without restriction from a third party which is lawfully in possession of such information and is not in breach of any agreement or any confidential relationship with the Disclosing Party; or
- (c) information which the Receiving Party can prove by suitable written documentation is or becomes public through no fault of the Receiving Party or third parties who received such information from the Receiving Party.





4. -Upon request of the Disclosing Party, the Receiving Party shall return to the Disclosing Party all Confidential Information supplied by the Disclosing Party hereunder in written or other tangible form including all copies thereof, and all documents which contain Confidential Information, and PHARMALLIANCE use its best endeavours to ensure return of any copies given to third parties pursuant to paragraph 2 of the Agreement

5. -Nothing in this Agreement shall be deemed by implication or otherwise to convey to the Receiving Party any proprietary, intellectual property, ownership or other right, title or interest in any Confidential Information of the Disclosing Party.

Nothing in this Agreement shall prevent the Disclosing Party from entering into any relationship with any third party, nor prevent the Disclosing Party from proceeding independently of the Receiving Party, in connection with the Confidential Information.

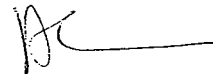
6. -This Agreement may only be amended by a written document signed by the Disclosing Party and the Receiving Party. The failure of either party to enforce any term of this Agreement shall not constitute a waiver of such term or any breach of such term, and shall not affect the right to require compliance with such term in the future. All waivers of any terms or breaches of this Agreement must be in writing and signed by the party against whom such waiver is asserted. The enforceability and interpretation of this Agreement shall be governed by Spanish law, without regard to principles of choice of law.

7. -The Receiving party hereby represents and warrants that it is permitted to enter into this Agreement and perform all of the obligations contemplated herein, and that this Agreement and its terms and obligations are not inconsistent with, or in violation of, any other obligation, contractual or otherwise, which it may have.

8. -A judicial determination that any term of this Agreement is unenforceable or invalid in whole or in part shall not affect the validity or enforceability of those terms not found to be unenforceable or invalid.

9. -The Disclosing Party may assign any of its rights or obligations under this Agreement. The Receiving Party shall not assign any of its right or obligations under this Agreement without the prior written consent of the Disclosing Party, and any purported assignment or transfer without such prior written consent shall be void.

10. -The Receiving Party hereby agrees and acknowledges that the disclosure of confidential information without the express written permission of the Disclosing Party will cause the Disclosing Party irreparable harm, and that any breach of threatened breach of this Agreement by the Receiving Party will entitle the Disclosing Party to injunctive relief, in addition to any other legal remedies available to the Disclosing Party, in any court of competent jurisdiction.

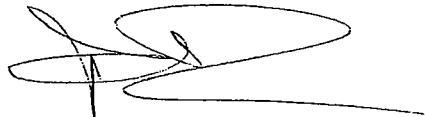


11. -The confidentiality and nondisclosure obligations set forth in Paragraph 2 of this Agreement shall expire five (10) years after the date of this Agreement. This Agreement constitutes the entire agreement between the parties with respect to the subject matter hereof and supersedes all prior agreements and understandings, oral or written, between the parties relating to the subject matter hereof.

IN WITNESS WHEREOF, the parties have executed this Agreement as of the date first set forth above.

**DISCLOSING PARTY :**

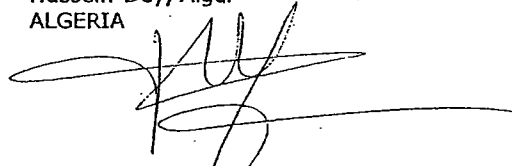
**LABORATORIOS BELMAC S. A.**  
C Teide 4, Planta Baja  
Polígono Empresarial La Marina  
28700 Madrid SPAIN



**By: Adolfo Herrera Malaga**  
**General Manager**

**RECEIVING PARTY :**

**PHARMALLIANCE**  
63 Rue Boudjema Moghni  
Hussein-Dey, Alger  
ALGERIA



**By: Amal Lamari**  
**General Manager**

B533

**From:** Paul Fitzgibbons  
**Sent:** Thu, 15 Nov 2001 20:48:38 GMT  
**To:** Jim Murphy (E-mail); Mike Price; Bob Gyurik (E-mail); Stote Bob (E-mail); Jordan Horvath  
**CC:**  
**BCC:**  
**Subject:** Project Status Report - 6 Nov

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Attached is the project status report from our 6 Nov meeting. The next meeting is scheduled for Tuesday, 20 Nov at 8:30 am.

Paul Fitzgibbons  
Bentley Pharmaceuticals, Inc.  
603-964-8006 (office) 603-964-6889 (fax)  
pfitzgibbons@bentleypharm.com

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**Bentley Pharmaceuticals**  
**Project Status Report – November 6, 2001**

PROJECT AND STATUS	ACTION
<p>1. Pfizer</p> <ul style="list-style-type: none"> <li>▪ Current Actions: <ul style="list-style-type: none"> <li>- First JWC meeting (7 Nov) postponed until 9 Nov. Bob and Paul to attend. Paul preparing draft budget. Fully signed agreement pending.</li> <li>- Dermtech - received proposal from Dermtech, proposal to be discussed at JWC meeting with Pfizer.</li> </ul> </li> </ul> <p><u>Note:</u> Basic Agreements pending/planned: 1) Research Collaboration Agreement; 2) License (or Platform) Agreement; and 3) Subscription (investment) Agreement.</p>	<p>Bob/Paul attend JWC Meeting, get signed agreement</p> <p>Bob continue to coordinate with Dermtech</p>
<p>2. GlaxoSmithKline (GSK)</p> <p>a) GSK (North Carolina) - Insulin</p> <ul style="list-style-type: none"> <li>▪ Joel emailed Jim: internal debate on insulin. No consensus yet. Mid-Nov for further decisions.</li> </ul> <p>b) GSK (Phila) – Musclar-Skeletal products</p> <ul style="list-style-type: none"> <li>▪ Jim, Bob G. and Paul met with Chau-Pin Lee in Collegeville, PA on 17 Oct. Looking for help on one <u>unspecified</u> drug. Need 1 mg delivered with 30 min on-set of action, transdermal or intranasal delivery. They are early-on in a long-haul project. Difficult at best and not high priority for us at this point. GSK discussing internally and they will get back to us.</li> </ul>	<p>Jim monitor</p> <p>No action at this time</p>
<p>3. Insulin – Development Issues</p> <p>a) <u>Supply</u> – Insulin supply from Diosynth. All OK for now.</p> <p>b) <u>Clinical Trials</u> - Phase I trial: Proof of Principle (normals), followed by the Phase II trial: Type 1 and 2 diabetics</p> <ul style="list-style-type: none"> <li>▪ Phase I at UNH Center for Health Enhancement (CHE) <ul style="list-style-type: none"> <li>- UNH IRB approval of protocol pending one outside reviewer from Dartmouth IRB. Bob S. monitor.</li> <li>- Paul working with UNH (Vic Sosa) for clinical trial contract and Tony T. for budget</li> <li>- Bob S. working insurance coverage (Tom Wilde)</li> </ul> </li> <li>▪ Schwartz Lab <ul style="list-style-type: none"> <li>- Project on hold pending completion of trial at CHE.</li> </ul> </li> </ul> <p>d) <u>Regulatory</u></p> <ul style="list-style-type: none"> <li>▪ IND will be submitted prior to follow-on Phase I/II with Schwartz Lab</li> </ul>	<p>Paul pursue contract &amp; budget.</p> <p>Bob S. work trial insurance.</p> <p>Bob Stote keep in touch with Schwartz lab.</p>
<p>4. Bio-Concept Laboratories</p> <ul style="list-style-type: none"> <li>▪ Sterile actuator issue: putting thru another two week study to evaluate</li> <li>▪ Received excellent progress report covering work to date.</li> </ul> <p><u>Note:</u> <u>Future ophthalmic research:</u> They asked for separate IP agreement in preparation for their submission of an SBIR by 1 Dec. <u>Need to discuss/resolve this, as we have no basic agreement with them as yet.</u></p>	<p>Bob/Paul continue to monitor progress</p> <p>Jim/Jordan to visit Frank Smith to talk ophthalmic collaboration</p>

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## Bentley Pharmaceuticals Project Status Report – November 6, 2001

PROJECT AND STATUS	ACTION
<p>5. Novartis</p> <ul style="list-style-type: none"> <li>▪ Anti-fungal lacquer <ul style="list-style-type: none"> <li>- Jim to talk to Bob Nissen today. Key factors are: 1) binding LOA (term sheet); 2) upfront cash needed ; 3) milestones; 3) royalties; 4) equity investment in Bentley ; and 5) timing.</li> <li>- Novartis wants to be involved in study design. Meeting at Novartis being planned for 19 Nov. (Bob Stote coordinating with Helmut Albrecht).</li> <li>- Need to resolve type of study: pilot or pivotal, cost, timeline, location for study. (Need to determine best course of action for U.S./Canada and Spain trials)</li> </ul> </li> <li>▪ Paracetamol (acetaminophen) - Jim also sent them summary data on clinical evaluation of paracetamol. Potential interest in sachet form.</li> </ul>	<p>Jim discuss with Bob Nissen</p> <p>Bob Stote confirm meeting with Helmut Albrecht</p> <p>Monitor any further interest with paracetamol</p>
<p>6. Gupta Clinical Trial</p> <ul style="list-style-type: none"> <li>▪ Bob to talk to Gupta this Friday to postpone 21 Nov visit to his lab. Reschedule any day Dec 10-13 if possible. Decision to conduct trial pending outcomes with Novartis (and possibly others).</li> </ul>	<p>Bob G. reschedule visit to Gupta lab in Toronto</p>
<p>7. Spain Phase III Lacquer Trial</p> <ul style="list-style-type: none"> <li>▪ Bob Stote and Paul talk to Nieves Hernando about requirements in Spain and discuss type of trial (Clotrimazole, ciclopirox, placebo?)</li> </ul>	<p>Bob S. and Paul talk to Nieves</p>
<p>8. Auxilium A<sup>2</sup></p> <ul style="list-style-type: none"> <li>▪ Testosterone in Men – Phase 3 in progress. Last patient planned on 19 Oct. NDA submission planned for 31 Dec. Reference country to be chosen at time of filing NDA.</li> <li>▪ Stanolone (DHT) – They are awaiting the 30 day stability on 6 formulations sent to them, will then go into Yucatan pigs, and then select 2 formulations to go into man with before making an acceptance decision.</li> <li>▪ Oxycodone – Bob G. to send them the oxycodone formulation that failed so they can look at it and then prepare to go to the next step.</li> </ul>	<p>Bob S. monitor Testo progress</p> <p>Bob S / Bob G monitor DHT progress</p> <p>Bob G. send oxy formulation</p>
<p>9. UAB Nail Lacquer Clinical Study</p> <ul style="list-style-type: none"> <li>▪ Anti-fungal nail lacquer – Phase I/II Trials on-going at UAB. Latest update received from Wendy: 31 Oct. Continue to monitor results.</li> </ul>	<p>Bob S. monitor progress</p>
<p>10. Dartmouth-Bentley NHIRC Grant – Testosterone in women with Fibromyalgia (FMS)</p> <ul style="list-style-type: none"> <li>▪ First 6 patients scheduled for final screening with Dr. Lin Brown, 5-9 Nov.</li> <li>▪ Clinical Trial is for 28 days with each patient</li> <li>▪ First 6 patients start trial together on Saturday 10 Nov with final blood draws on Day 28, Saturday 9 Dec. Other patients are needed: target of 12 patients total.</li> </ul>	<p>Bob/Paul monitor progress</p>
<p>11. UNH Projects – Summary</p> <ul style="list-style-type: none"> <li>▪ Project 1- Yvon Durant: Intranasal delivery, membrane transport. Most likely need to extend this, even if we fund it alone. Will look for NHIRC extension.</li> <li>▪ Project 2 – Roger Wells: Delivery studies (pigs: testo, DHT, GnRH)</li> </ul>	<p>Bob G./ Paul monitor progress</p>

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**Bentley Pharmaceuticals**  
**Project Status Report – November 6, 2001**

PROJECT AND STATUS	ACTION
<ul style="list-style-type: none"> <li>Project 3 – Stacia Sower: Peptide delivery (GnRH transdermally and intranasally. (Note: Roger Wells working in conjunction with Stacia to conserve resources)</li> </ul>	
12. Reckitt-Benckiser <ul style="list-style-type: none"> <li>Reformulating paracetamol sachet for taste masking. Asked for more samples with different flavoring. Expect decision by mid-November.</li> </ul>	Jim/Adolfo keep in touch with Reckitt
13. Sanofi Synthelabo - Paracetamol tablets <ul style="list-style-type: none"> <li>Reformulating again for faster dissolution</li> </ul>	Jim / Adolfo monitor
14. CPE-215 EDMF – Haarmann & Reimer (H&R) <ul style="list-style-type: none"> <li>EDMF: Currently not pursuing EDMF for CPE-215</li> <li>Need to complete the CDA with them.</li> </ul>	Jordan respond to H&R on CDA
15. New Patents <ul style="list-style-type: none"> <li><u>Patents – Spain</u> <ol style="list-style-type: none"> <li>1<sup>st</sup> Patent – Submitted P-2000,02685 (General procedure – Vacuum and Granulation for other products.</li> <li>2<sup>nd</sup> Patent – Submitted P-2000,002797 (Tablet formulation for Omeprazole and other gastric sensitive drugs – Direct compression.</li> <li>3<sup>rd</sup> Patent – Organic formulation process for Omeprazole. Patent P-2001,00825. (also protection from Ethypharm).</li> <li>4<sup>th</sup> Patent – Aqueous Process - a patent extension of the tablet formulation patent from last year (P-2000,002797). To be submitted early November 2001.</li> <li>5<sup>th</sup> Patent – New procedure for tablets – direct compression. Plan to submit in December 2001.</li> <li>PCT for Paracetamol filed</li> </ol> </li> <li><u>Patents – Bentley</u> <ol style="list-style-type: none"> <li>Intranasal Insulin Patent – Bob G. filed the provisional in U.S. in June '01.</li> <li>Lacquer PCT Patent issued 23 Aug; all claims allowed</li> </ol> </li> </ul>	Continue to monitor  Press release on Spain patents soon
16. Insurance Issues <ul style="list-style-type: none"> <li>Mike sent summary of coverages in Europe to Tom Wilde (Gallagher Insurance). Wilde will review this, and he will also talk to</li> <li>Issue of confidentiality – Are insurance companies bound by confidentiality?</li> <li>Insulin trials insurance – Need to send contract/agreement to Tom Wilde with agreed upon insurance/indemnity clauses.</li> </ul>	Mike follow-up on confidentiality question  Paul working contract with UNH
17. BOD Meeting Schedule <ul style="list-style-type: none"> <li>Next BOD Meeting is 7-8 Nov in Philadelphia, PA. Mike has the agenda. Jim to provide his presentation evening of 7 Nov.</li> <li>Jan 30<sup>th</sup> is date for the winter meeting in Spain (fly out separate flights 28<sup>th</sup> or 29<sup>th</sup>)</li> </ul>	Attend meeting

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## Bentley Pharmaceuticals Project Status Report – November 6, 2001

PROJECT AND STATUS	ACTION
<b>18. Tax Planning</b> <ul style="list-style-type: none"> <li>Local Tax – Conference call occurred Friday 12 Oct with Mike/Jordan and Brian Gallagher, and Deloitte &amp; Touche. Follow-up conference call planned.</li> <li>Federal / Int'l Tax – Need to look at tax consequences of transferring IP from subsidiary (Spain) to parent (Bentley). Brian Gallagher looking into this.</li> </ul> <p><b>Note: Tax Planning is on agenda for BOD meeting 7-8 Nov</b></p>	Mike / Jordan discuss prior to BOD meeting
<b>19. Cambrex</b> <ul style="list-style-type: none"> <li>Discussion/negotiation in progress. Various funding proposals being discussed: <ul style="list-style-type: none"> <li>Cambrex wants to take a 9.9% interest in Bentley.</li> <li>Cambrex provide ½ cash funding upfront along with our dossiers, ANDAs, and IP</li> <li>Cambrex providing stock (potential selling by Bentley for cash)</li> <li>Jim proposed \$5M per year for 5 yrs</li> <li>Provide a list of our Spanish products as candidates for generic submission in U.S. under the JV.</li> </ul> </li> </ul>	Define what we want from them after BOD meeting, then provide term sheet
<b>20. RIT (GSK in Belgium) – Vaccines:</b> Bob Stote follow-up with RIT	Bob Stote follow-up with RIT
<b>21. Bristol Myers Squibb – Review of lacquer coming up.</b> CDA is pending. BMS moving very slowly.	Jordan track CDA
<b>22. Chatham</b> <ul style="list-style-type: none"> <li>Pending meeting to discuss lacquer (OTC) and other topicals (diclofenac). Need to send information, product profiles. Emphasize paracetamol.</li> </ul>	Send info to them
<b>23. Ciprofloxacin</b> <ul style="list-style-type: none"> <li>Jordan spoke with Senator Smith staffer who deals with DoD, no further progress.</li> <li>Paul to call Dept of Defense agency to check on policy of DoD purchasing non FDA approved drugs.</li> </ul>	Paul call DoD for policy info
<b>24. Pharmacia &amp; UpJohn</b> <ul style="list-style-type: none"> <li>Pharmacia has expressed strong interest in our lacquer</li> <li>Paul sent list of Pharmacia/Searle drugs for application of CPE-215 sent to Herb Brotspies</li> <li>Due diligence visit to Bentley scheduled for 26 Nov.</li> </ul>	Prepare for due diligence visit
<b>25. Herron</b> <ul style="list-style-type: none"> <li>Wants to license paracetamol for Australia and Pacific Rim. Adolfo sent term sheet.</li> </ul>	Adolfo action
<b>26. Procter &amp; Gamble</b> <ul style="list-style-type: none"> <li>Called to ask for our help to test a topical product (regional, non-systemic, lipophilic tendencies, 200-300 MW)</li> <li>Need to complete CDA and MTA</li> </ul>	Jordan complete CDA
<b>27. DUSA Pharm.</b> <ul style="list-style-type: none"> <li>Visited us 26 Oct. Interested in photo-active compounds with CPE-215. CDA completed.</li> </ul>	Jim monitor

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B538



**Bentley Pharmaceuticals**  
**Project Status Report – November 6, 2001**

PROJECT AND STATUS	ACTION
28. Perrigo Pharm. * Interested in topical NSAIDs. CDA sent to them.	Jim monitor
<b>END LIST- OTHER POTENTIALS</b> McNeil – Lacquer Schering AG (Berlex in U.S.) – Derm. products, HRT PLR – Potential switch to other firm TEVA – Potential acquisition of Bayvit	

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**BENTL022459**  
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B539

## Formulation Needs

- Radiolabel Nail Assay (BAGEL) + Skin Terbinafine
- Clotrazole (Radiolabel) - Rutgers C<sup>14</sup>

## Clinical Supplies (DPT or Novartis)

Due Diligence needed at Contractor  
By Jan - 02Stability - 3 month stability  
3 commercial BATCHES (10%)

- Conf. Call
- MTA
- Formulation

In Vitro - Nail - Novartis

In Vitro - Skin - Berkey

Spain - Adolfo  
20 NOV 01

CPE-215 - DATA NEEDED

Ethypharm - Adolfo Basilio

26<sup>th</sup> Meeting @ Ethypharm

Patents are now being reviewed

TEVA - DOSSIERS deficient

Pravastatin - 50K tablet  
but 100K tablet run  
necessary

B540

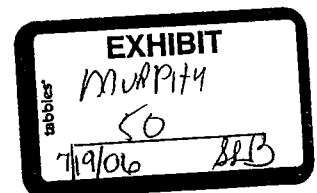
**From:** Paul Fitzgibbons  
**Sent:** Fri, 30 Nov 2001 18:50:36 GMT  
**To:** Jim Murphy; Mike Price; Bob Gyurik; 'Stote Bob (E-mail)'; Jordan Horvath  
**CC:**  
**BCC:**  
**Subject:** Project Status Report - 20 Nov

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Attached is the Project Status Report from our 20 Nov meeting. Next meeting will be Thurs 6 Dec at 8:30.

Paul Fitzgibbons  
Bentley Pharmaceuticals, Inc.  
603-964-8006 (office) 603-964-6889 (fax)  
pfitzgibbons@bentleypharm.com

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B541



## Bentley Pharmaceuticals Project Status Report – November 20, 2001

PROJECT AND STATUS	ACTION
<p>1. Pfizer</p> <ul style="list-style-type: none"> <li>▪ Research Agreement signed. Collaborating on press release.</li> <li>▪ Bob and Paul attended first JWC meeting on 19 Nov. Minutes in progress from Keith.</li> <li>▪ Formulation work pending: 2 veterinary (Doramectin/Selamectin), 1 sexual health, and 2 antivirals. Budget – \$150K upfront approved by JWC. Budget total of \$310K under review.</li> <li>▪ DermTech - Need to align proposed in vitro testing with approach agreed upon at JWC. Also need to complete a research agreement with DermTech.</li> </ul> <p><u>Note:</u> Basic Agreements pending/planned: 1) Research Collaboration Agreement; 2) License (or Platform) Agreement; and 3) Subscription (investment) Agreement.</p>	<p>Bob begin formulation devel.</p> <p>Resolve budget approval</p> <p>Bob coordinate with DermTech</p>
<p>2. GlaxoSmithKline (GSK)</p> <ul style="list-style-type: none"> <li>▪ GSK (North Carolina) - Insulin               <ul style="list-style-type: none"> <li>- Further progress pending results of insulin clinical study (UNH/CHE).</li> </ul> </li> <li>▪ GSK (Phila) – Musclar-Skeletal products               <ul style="list-style-type: none"> <li>- Meeting held in Collegeville, PA on 17 Oct. GSK discussing internally and they will get back to us. No further action at this time.</li> </ul> </li> <li>▪ GSK – Ian Buxton wants us to do formulation work for transdermal product. Need to draft a proposal.</li> </ul>	<p>Jim keep in touch with Joel</p> <p>No action with GSK Phila</p> <p>Bob G./Jim work up proposal for Ian</p>
<p>3. Insulin – Development Issues</p> <p>a) <u>Supply</u> – Insulin supply from Diosynth. All OK for now.</p> <p>b) <u>Clinical Trials</u> -</p> <ul style="list-style-type: none"> <li>▪ Proof of Principle Trial (in normals) at UNH Center for Health Enhancement (CHE)               <ul style="list-style-type: none"> <li>- Obtained budget from UNH (approx \$30K). Contract in-work with Jordan. Insurance to be worked along with contract. Bob S. to obtain \$2M quote from Tom Wilde.</li> <li>- Submitted revised protocol with answers to IRB questions (21 Nov); IRB meets Friday 30 Nov.</li> <li>- <u>Inveresk</u> – Bob S. coordinating with Inveresk as alternative CRO if CHE falls through. Cost for Inveresk is \$60K. Faxed contract and proposal in hand. Dec 6<sup>th</sup> is deadline for us to deliver necessary data to Inveresk for them to complete trial in Jan.</li> </ul> </li> <li>▪ Schwartz Lab – for Type 1 and Type 2 Diabetics               <ul style="list-style-type: none"> <li>- Project on hold pending completion of trial at CHE.</li> </ul> </li> </ul> <p>d) <u>Regulatory</u></p> <ul style="list-style-type: none"> <li>▪ IND will be submitted prior to follow-on Phase I/II with Schwartz Lab</li> </ul>	<p>Paul / Jordan coordinate CHE contract</p> <p>Bob S. / Paul monitor IRB approval</p> <p>Bob S. coordinate with Inveresk</p> <p>Bob S. keep in touch with Schwartz lab.</p>
<p>4. Bio-Concept Laboratories</p> <ul style="list-style-type: none"> <li>▪ <u>Insulin</u> - Budget increase of \$6K for EPO sterilization for insulin manufacturing.</li> <li>▪ <u>Ophthalmic research</u> – Jim/Bob G. to visit Frank Smith on 21 Nov. Two topics: a) Ophthalmic research collaboration, and b) acquisition potential.</li> </ul>	<p>Bob G. follow-up on progress and schedule</p> <p>Jim / Bob G. to visit Frank Smith 21 Nov</p>

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# **Bentley Pharmaceuticals** **Project Status Report – November 20, 2001**

PROJECT AND STATUS	ACTION
<p>5. Novartis</p> <ul style="list-style-type: none"> <li>▪ Anti-fungal Nail Lacquer <ul style="list-style-type: none"> <li>- Successful meeting held with Novartis on 19 Nov. Jordan to follow-up with Bob Nissen to clarify decisions made and to discuss MTA.</li> <li>- Study with Clotrimazole, Terbinafine, and Naftifine is planned. Awaiting action by Novartis for further progress. Conference call with Basel to be held.</li> </ul> </li> <li>▪ Paracetamol (acetaminophen) - Jim provided samples to Mark Schobel at 19 Nov meeting. Prefer different taste.</li> </ul>	<p>Jordan talk to Bob Nissen (decisions and MTA)</p> <p>Jim monitor interest in paracetamol</p>
<p>6. Gupta Nail Lacquer Clinical Trial</p> <ul style="list-style-type: none"> <li>▪ Paul emailed Gupta to postpone meeting to Dec 10-13 timeframe. Bob G. to call Gupta and delay further until we decide what/when type of trial will be performed.</li> </ul>	<p>Bob G. call Gupta to delay</p>
<p>7. Spain Phase III Lacquer Trial</p> <ul style="list-style-type: none"> <li>▪ Received email from Adolfo re. documentation needed on CPE-215 as a fragrance and excipient. Bob G. to call Jim Van Dyke at H&amp;R to ask for a monograph for CPE-215.</li> <li>▪ Need to resolve whether we are doing a study in Spain or not. Value? Type actives to include: Clotrimazole, Ciclopirox, Terbinafine?</li> </ul>	<p>Jim/Bob G. visit Spain week of 26 Nov</p>
<p>8. Haarmann &amp; Reimer (H&amp;R) – Supply of CPE-215</p> <ul style="list-style-type: none"> <li>▪ Currently not pursuing EDMF for CPE-215</li> <li>▪ Paul obtained RIFM/FEMA data on CPE-215. Spain asking for monograph.</li> <li>▪ Need to complete the CDA with them.</li> </ul>	<p>Jordan respond to H&amp;R on CDA</p> <p>Monograph?</p>
<p>9. Auxilium A<sup>2</sup></p> <ul style="list-style-type: none"> <li>▪ Testosterone in Men – NDA submission planned for 31 Dec. Reference country to be chosen at time of filing NDA. Bob G. to assist with NDA 4-6 Dec.</li> <li>▪ Stanolone (DHT) – After 30 day stability on 6 formulations sent to them, will go into Yucatan pigs, then select 2 formulations to go into man before making an acceptance decision. Issue of “acceptance” discussed (\$25K being held up).</li> <li>▪ Oxycodone – Regarding formulation, intranasal route is questionable – work on Oxy tabled for now.</li> </ul>	<p>Bob S. monitor Testo progress</p> <p>Need to resolve “acceptance” issue</p> <p>Bob S / Bob G monitor DHT progress</p>
<p>10. UAB Nail Lacquer Clinical Study</p> <ul style="list-style-type: none"> <li>▪ Anti-fungal nail lacquer – Phase I/II Trials on-going at UAB. Latest update received from Wendy: <u>31 Oct</u>. Continue to monitor results.</li> </ul>	<p>Bob S. monitor progress</p>
<p>11. Dartmouth-Bentley NHIRC Grant – Testosterone in women with Fibromyalgia (FMS)</p> <ul style="list-style-type: none"> <li>▪ First 5 patients started trial on 10 Nov. Initial data looks good – doubled baseline testosterone levels after 24 hrs.</li> <li>▪ Clinical Trial is for 28 days with each patient. Additional patients are needed. The target is 12 patients total.</li> </ul>	<p>Bob/Paul monitor progress</p>

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## Bentley Pharmaceuticals Project Status Report – November 20, 2001

PROJECT AND STATUS	ACTION
<b>12. UNH Projects – Summary</b> <ul style="list-style-type: none"> <li>▪ Project 1 - Yvon Durant: Intranasal delivery, membrane transport. New person, Weihong Gau, is now assisting along with Zhengmau. Will be applying for NHRC grant extension or possibly new grant. Current project ends 30 May 2002.</li> <li>▪ Project 2 – Roger Wells: Delivery studies (pigs: testo, DHT, GnRH).</li> <li>▪ Project 3 – Stacia Sower: Peptide delivery (GnRH transdermally and intranasally. (Note: Roger Wells working in conjunction with Stacia to conserve resources).</li> </ul>	Bob G./ Paul monitor progress
<b>13. Reckitt-Benckiser</b> <ul style="list-style-type: none"> <li>▪ Reformulating paracetamol sachet for taste masking. Asked for more samples with different flavoring. Jim will follow up.</li> </ul>	Jim to email again
<b>14. Sanofi Synthelabo - Paracetamol tablets</b> <ul style="list-style-type: none"> <li>▪ Reformulating again for faster dissolution. Jim will follow-up.</li> </ul>	Jim to email again
<b>15. New Patents</b> <ul style="list-style-type: none"> <li>▪ <u>Patents – Spain</u> <ol style="list-style-type: none"> <li>a) 1<sup>st</sup> Patent – Submitted P-2000,02685 (General procedure – Vacuum and Granulation for other products.</li> <li>b) 2<sup>nd</sup> Patent – Submitted P-2000,002797 (Tablet formulation for Omeprazole and other gastric sensitive drugs – Direct compression.</li> <li>c) 3<sup>rd</sup> Patent – Organic formulation process for Omeprazole. Patent P-2001,00825. (also protection from Ethypharm).</li> <li>d) 4<sup>th</sup> Patent – Aqueous Process - a patent extension of the tablet formulation patent from last year (P-2000,002797). To be submitted early November 2001.</li> <li>e) 5<sup>th</sup> Patent – New procedure for tablets – direct compression. Plan to submit in December 2001.</li> <li>f) PCT for Paracetamol filed</li> </ol> </li> <li>▪ <u>Patents – Bentley</u> <ol style="list-style-type: none"> <li>a) Intranasal Insulin Patent – Bob G. filed the provisional in U.S. in June '01.</li> <li>b) Lacquer PCT issued 23 Aug; all claims allowed (will need to follow up with patent applications for appropriate countries)</li> </ol> </li> </ul>	Jordan and Bob G. to review patent issues. Jordan to have more oversight on patents  Jordan to visit Spain week of 6 Jan. Jordan call to coordinate
<b>16. Insurance Issues</b> <ul style="list-style-type: none"> <li>▪ Tom Wilde passed issue on coverages in Europe to an international rep within Gallagher. He will be getting back to Mike.</li> <li>▪ Issue of confidentiality – Tom Wilde believes they are bound by ethical practices, but is willing to sign a confidentiality agreement.</li> <li>▪ Insulin trial insurance – Need to send contract to Tom Wilde with agreed upon insurance/indemnity clauses. Need quote for \$2M in lieu of \$500K.</li> </ul>	Mike monitor international coverage issues  Paul / Bob S. to provide insulin trial contract to Tom Wilde  Bob S. get quote for \$2M on insulin trial.

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## Bentley Pharmaceuticals Project Status Report – November 20, 2001

PROJECT AND STATUS	ACTION
<b>17. Tax Planning</b> <ul style="list-style-type: none"> <li>Tax issues discussed at 7-8 Nov BOD Meeting. Jordan/Mike drafting document that addresses all issues and plan of action to minimize tax consequences with revenue in U.S. and transfer of IP between Bentley and subsidiaries.</li> </ul>	Prepare tax paper for BOD
<b>18. Cambrex</b> <ul style="list-style-type: none"> <li>Discussion/negotiation in progress. <u>Jim to call Tom Bird today.</u> Various funding proposals being discussed: <ul style="list-style-type: none"> <li>Cambrex wants to take a 9.9% interest in Bentley.</li> <li>Cambrex provide ½ cash funding upfront along with our dossiers, ANDAs, and IP</li> <li>Cambrex providing stock (potential selling by Bentley for cash)</li> <li>Jim proposed \$5M per year for 5 yrs</li> <li>Provide a list of our Spanish products as candidates for generic submission in U.S. under the JV.</li> </ul> </li> </ul>	Jim call Tom Bird  Define what we want from them after BOD meeting, then provide term sheet
<b>19. RIT (GSK in Belgium) – Vaccines.</b> RIT point of contact tied up with small pox issues. Bob S. continue to try to contact.	Bob Stote follow-up with RIT
<b>20. Bristol Myers Squibb – Review of lacquer coming up.</b> CDA is pending. BMS moving very slowly. Didn't hear back from David Voltz. Jim to call him.	Jim call Voltz  Jordan track CDA
<b>21. Chattem</b> <ul style="list-style-type: none"> <li>Pending meeting to discuss lacquer (OTC) and other topicals (diclofenac). Need to send information, product profiles. Emphasize paracetamol.</li> </ul>	Send info to them
<b>22. Pharmacia</b> <ul style="list-style-type: none"> <li>Primary interest is our anti-fungal nail lacquer.</li> <li>Due diligence visit to Bentley scheduled for 26 Nov. Paul / Bob S. reviewing due diligence list sent by Pharmacia.</li> <li>Paul sent list of Pharmacia/Searle drugs for application of CPE-215 to Herb Brotspies.</li> </ul>	Prepare for due diligence visit
<b>23. Herron</b> <ul style="list-style-type: none"> <li>Wants to license paracetamol for Australia and Pacific Rim. Adolfo sent term sheet. Jim to get update from Adolfo during 27 Nov visit to Spain.</li> </ul>	Jim talk to Adolfo during 27 Nov visit to Spain
<b>24. Procter &amp; Gamble</b> <ul style="list-style-type: none"> <li>Erik Loomis asked for our help formulating a topical product (regional, non-systemic, lipophilic tendencies, 200-300 MW).</li> <li>Our initial proposal above their budget. Need revised proposal with less work (no Franz cell, or other in-vitro testing). Also need to resolve CDA issue: 1-way or 2-way?</li> </ul>	Jordan to follow-up on CDA
<b>25. DUSA Pharm.</b> <ul style="list-style-type: none"> <li>Interested in photo-active compounds with CPE-215. Visited us 26 Oct. Haven't heard from them since meeting. Jim to make follow-up call</li> <li>CDA completed.</li> </ul>	Jim follow-up

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## Bentley Pharmaceuticals Project Status Report – November 20, 2001

PROJECT AND STATUS	ACTION
26. Perrigo Pharm. ▪ Interested in topical NSAIDs. CDA completed. Need to send product profiles (as with Chattem). Jim to call them today.	Jim call them
27. Banner Pharm. (North Carolina) ▪ Interested in testing/research of paracetamol. Willing to sign CDA.	
28. Bayer AG ▪ Interested in our nail lacquer. Bayer AG has product called Canesten® (clotrimazole) that is the market-leading antifungal in Europe. ▪ Want to perform due diligence on our lacquer. Jim to send summary on lacquer performance. Follow-up afterwards with CDA.	Jim send information summary
29. BOD Meeting Schedule ▪ Strategic Planning and Compensation Committee meetings planned for 3 Dec in Phila. ▪ Jan 30 <sup>th</sup> is date for the winter meeting in Spain (fly out separate flights 28 <sup>th</sup> or 29 <sup>th</sup> )  <u>Other meetings:</u> The spring shareholder meeting is tentatively scheduled for May 22 <sup>nd</sup> , don't want AMEX Board Rm, possibly the Princeton Club. Jordan check with Miguel.	Attend 3 Dec committee meetings in Phila  Jordan call Miguel on availability of Princeton Club for shareholder mtg
END LIST- OTHER POTENTIALS	
McNeil – Lacquer Schering AG (Berlex in U.S.) – Derm. products, HRT PLR – Potential switch to other firm TEVA – Potential acquisition of Bayvit	

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SPAIN NGW OFFICE Meeting 27 Nov.

## Ethypharm

Cancelled Contract - failed to provide

1. Std machine
2. Envir. Scrubbers
3. Aquarius Formula
4. Organic - does not work
5. Contract Dec. 2000

Lansoprazole - 2005 Patent EU

Patent checked by Aquila -

## PHARMALLANCE (Algonia)

Ompresate  
Simvastatin  
Enalapril

Jose Maria - 30 Jan

Dr Clemente - Sept

Dr. F Borungur - Jan

Laura - Nov 30

Lewis Cabahat - Full Time May / June

Ethypharm - why not purchase API  
from others now claiming  
they have not done what  
they said they would.

Synton - Zolpidem  
Transfer 2 to Belmar  
Marketing Approval - 1 month  
to transfer

Herron  
Sanofi  
Reckitt } No response

- \* Pentoxifylline - Down approved
- \* RatiDine - Dec approve expected
- \* (Claritin) - approved
- \* Zyrtec - Submitted MOA  
expect Jan.

Simvastatin - 12 Approved  
8 Manuf. by Belmar  
Bivogal - Supply API  
(Teva)

Omeprazole - Contact Andrx

Lacquer - Manufacturer 3 shifts probable  
Manuf. 2 Shifts - Packaging Limitation  
May Sell Plant. Ovata 120 mil. 3.2x Sales

- \* Loratadine (Claritin) - approved
- \* Ibuprofen 800 Approved will be  
only one on mkt



LABORATORIOS BELMAC  
 Polígono de Malpica  
 Calle C num. 4  
 50016 ZARAGOZA  
 Espagne

Saint Cloud, December 12, 2001

Via Facsimile and courier

For the attention of Mr HERRERA

Dear sir,

As our subcontractor using our technology to produce our product namely Omeprazol, you have a clear obligation to deliver suitable product on a timely basis. Moreover, you have an obligation to inform us of any possible problems which could impact on the quantity or quality of on-time performance of appropriate product with any of our licensees.

As you are clearly aware, we have had unacceptable delays resulting from your failure to deliver our product omeprazol, to our customers. Indeed, we have recently lost one of our main licensees, Pharmalliance in Algeria.

You have also failed to respond to our repeated inquiries and questions concerning this over-all matter. Specifically, we have received no information concerning your manufacturing activities and delivery schedules or problems with our licensees. Indeed, since October 15<sup>th</sup>, 2001 our customer service representatives have repeatedly tried to organize a meeting with Mr Antonio Cabo de Villa without success.

This situation is intolerable and very damaging to Ethypharm both in terms of Business image as well as lost of sales and revenue due to your failure to perform.

<b>Siège Social</b> 21, rue Saint Matthieu F-78550 Houdan Tél : + 33 - 1 30 88 17 20 Fax : + 33 - 1 30 88 17 30	<b>Head Office</b> 194, Bureaux de la Colline - Bât. D F-92213 Saint-Cloud Cedex Tél : + 33 - 1 41 12 17 20 Fax : + 33 - 1 41 12 17 30	<b>Site R &amp; D - Z.I. de Saint Arnoult</b> F-28170 Châteauneuf-en-Thymerrain Tél : + 33 - 2 37 65 88 00 Fax : + 33 - 2 37 51 02 88	<b>Site R &amp; D - 1900, Route des Crêtes</b> Les Collines de Sophia F-06560 Valbonne Tél : + 33 - 4 92 96 09 59 Fax : + 33 - 4 92 96 09 60	<b>Site R &amp; D - Châteauneuf</b> 218-228, Av. du Haut-Lévêque F-33600 Pessac Tél : + 33 - 5 57 26 56 76 Fax : + 33 - 5 57 26 56 77
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EP 004853

